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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,094	09/12/2003	Kirsty Jane Dodgson	875.092US1	7668

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,094	DODGSON, KIRSTY JANE	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S-a-d

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 15-19, 23 and 25-26 are drawn to a method to detect *vanA* in a sample comprising detecting or determining the presence or amount of hybrid formation, classified in class 435, subclass 6.

II. Claims 2, 15-16, 20-22, 24 and 27 are drawn to a method to detect *vanB* in a sample comprising detecting or determining the presence or amount of hybrid formation, classified in class 530, subclass 388.21.

III. Claims 3, 5-7, 15-19, 23 and 25-26 are drawn to a method to detect *vanA* in a sample comprising detecting or determining the presence or amount of amplified nucleic acid, classified in class 536, subclass 24.3.

IV. Claims 4, 10-12, 15-16, 20-22, 24-25 and 27 are drawn to a method to detect *vanB* in a sample comprising detecting or determining the presence or amount of amplified nucleic acid, classified in class 536, subclass 24.32.

V. Claims 28 and 31 are drawn to a method to detect *vanA* nucleic acid and *vanB* nucleic acid in a sample comprising detecting or determining the presence or amount of hybrid formation, classified in class 435, subclass 464.

VI. Claims 29-31 are drawn to a method to detect *vanA* nucleic acid and *vanB* nucleic acid in a sample comprising detecting or determining the presence or amount of amplified nucleic acid, classified in class 435, subclass 91.2.

VII. Claims 32, 34, 36 and 42 are drawn to an oligonucleotide composition comprising sequences substantially corresponding to the *vanA* gene, classified in class 435, subclass 91.1.

VIII. Claims 33, 35-36 and 43 are drawn to an oligonucleotide composition comprising sequences substantially corresponding to the *vanB* gene, classified in class 514, subclass 44.

IX. Claims 37-41 are drawn to a kit comprising an oligonucleotide specific for a *vanA* gene and/or a *vanB* gene in a test sample, classified in class 435, subclass 287.2.

2. The inventions are distinct, each from the other because of the following reasons:

(i) Inventions I, II, III, IV, V and VI are related as distinct methods because they are different methods with different method steps; reagents; functions and each result in different final outcomes. First, the instant specification does not disclose that these methods would be used together, rather the specification beginning at page 4 states that the methods are separate and distinct embodiments. The methods are all unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs its function using a structurally and functionally divergent material. For instance, the use of

at least one *vanA* and *vanB* specific oligonucleotide primers to detect or determine the presence or amount of amplified nucleic acid, is not necessary to practice the other methods. In this case, group VI is separate and distinct, from groups I, II, III, IV or V since only group VI comprises the use of at least one *vanA* and *vanB* specific oligonucleotide primers. Furthermore, only group I detects *vanA* in a sample by detecting or determining the presence or amount of hybrid formation. This method is separate and distinct from any other method. Therefore, each method is divergent with respect to the amounts of reagents used and their associated steps. For these reasons the inventions I, II, III, IV, V and VI are patentably distinct.

Furthermore, searching the inventions of groups I, II, III, IV, V and VI, would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A method to detect *vanA* nucleic acid and *vanB* nucleic acid in a sample comprising detecting or determining the presence or amount of hybrid formation, requires a different search, than the other methods. Thus, a search drawn to a method to detect *vanA* nucleic acid and *vanB* nucleic acid in a sample comprising detecting or determining the presence or amount of hybrid formation, is not necessary for a determination of novelty and unobviousness of the method of group III which comprises detecting or determining the presence or amount of amplified nucleic acid. Furthermore, the method of group VI may be known even if the method of group I is novel. In addition, the technical literature search for the method of group I and the method of groups II-VI are not coextensive, since, for instance, the method group I may be characterized in the technical literature prior to discovery of the method of group III.

(ii) Inventions VII, VIII and IX are patentably different products. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions. Group VII is drawn to an oligonucleotide composition comprising sequences substantially corresponding to the *vanA* gene, Group VIII is drawn an oligonucleotide composition comprising sequences substantially corresponding to the *vanB* gene, and Group IX is drawn to kit comprising an oligonucleotide specific for a *vanA* gene and/or a *vanB* gene in a test sample. The group directed to the oligonucleotide are physically, structurally functionally different, and are therefore patentably distinct, each group from the other. For instance, the oligonucleotide composition comprising sequences substantially corresponding to the *vanA* gene is unlike the substrate of Group VIII. The oligonucleotide composition of group VII is drawn to the *vanA* gene which is unlike the groups VIII and IX. Therefore, one group is not required to practice the other. Each group comprises separate and distinct products that are not disclosed as being essential to the utility of the invention.

Furthermore, searching the inventions of groups VII, VIII and IX would impose a serious search burden. The inventions have a separate status in the art as shown by their distinct structure. Thus different proteins require different searches. An oligonucleotide sequence search is not necessary for a determination of novelty and unobviousness of another unrelated oligonucleotide. Moreover, a search of group VIII

is not required to identify the kit of group IX. Furthermore, the kit of group IX may be known even if the oligonucleotide of group VIII is novel. In addition, the technical literature search for the kit of group XI and the oligonucleotide of group VII are not coextensive, e.g., the oligonucleotide of group VII may be characterized in the technical literature prior to discovery of the kit of group IX.

(iii) Inventions I-VI and VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide composition of group VII can be practiced with a materially different process such as with a method of synthesizing primers. Moreover, the method of group I only detects or determines the presence or amount of hybrid formation. Therefore, the inventions have been shown as distinct.

Searching the inventions of groups I-VI and VII-IX together would impose serious search burden. The inventions of groups I-VI and VII-IX have acquired a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the oligonucleotide compositions and the method of detection or determination are not coextensive. Group VIII encompasses an oligonucleotide composition, and therefore is not required for the search of groups I, III or V. In contrast, the search for groups II would require a text search for a method comprising

determining the presence or amount of amplified nucleic acid and would not necessarily encompass a search for the other composition groups. Moreover, even if the oligonucleotide composition were known, the method comprising determining the presence or amount of amplified nucleic acid may be novel and unobvious in view of the preamble or active steps.

(iv) Inventions I, II, III, IV, V, VI, VIII and IX are unrelated because these methods and products are not used or otherwise involved in any of the above recited methods.

3. The inventions of Groups I-IX have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-IX together.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
July 26, 2006